

in a regulation, CMS ruling, or other interpretive rules, general statements of policy, and rules of agency organization, procedure, or practice established by CMS, whether made in response to judicial precedent or otherwise, is not a basis for reopening a CMS or intermediary determination, an intermediary hearing decision, a CMS reviewing official decision, a Board decision, or an Administrator decision, under this section.

(3) *Reopening by CMS or intermediary of determination currently on appeal to the Board or Administrator.* CMS or an intermediary may reopen, on its own motion or on request of the provider(s), a Secretary or intermediary determination that is currently pending on appeal before the Board or Administrator.

(i) The scope of the reopening may include any matter covered by the determination, including those specific matters that are appealed to the Board or the Administrator.

(ii) The intermediary must send a copy of the notice required under § 405.1887(a) to the Board or to the Administrator, through the Office of the Attorney Advisor, specifically informing that the matter(s) to be addressed by the reopening is currently under appeal to the Board or to the Administrator or is covered by the same determination that is under appeal.

(4) *Reopening of determination within the time for appealing that determination to the Board.* CMS or an intermediary may reopen, on its own motion or on request of the provider(s), a Secretary or intermediary determination for which no appeal was taken to the Board, but for which the time to appeal to the Board has not yet expired, by sending the notice specified in § 405.1887(a) of this subpart.

[73 FR 30265, May 23, 2008]

**§ 405.1887 Notice of reopening; effect of reopening.**

(a) In exercising its reopening authority under § 405.1885, CMS (for Secretary determinations), the intermediary or the reviewing entity, as applicable, must provide written notice to all parties to the determination or decision that is the subject of the reopening. Notices of—

(1) Reopening by a CMS reviewing official or the Board must be sent promptly to the Administrator.

(2) Intermediary reopenings of determinations that are currently pending before the Board or the Administrator must meet the requirements specified in § 405.1885(c)(3) and (c)(4) of this subpart.

(b) Upon receipt of the notice required under § 405.1887(a) of this subpart, the parties to the prior Secretary or intermediary determination or decision by a reviewing entity, as applicable, must be allowed a reasonable period of time in which to present any additional evidence or argument in support of their positions.

(c) Upon concluding its reopening, CMS, the intermediary or the reviewing entity, as applicable, must provide written notice promptly to all parties to the determination or decision that is the subject of the reopening, informing the parties as to what matter(s), if any, is revised, with a complete explanation of the basis for any revision.

(d) A reopening by itself does not extend appeal rights. Any matter that is reconsidered during the course of a reopening, but is not revised, is not within the proper scope of an appeal of a revised determination or decision (as described in § 405.1889 of this subpart).

[73 FR 30266, May 23, 2008]

**§ 405.1889 Effect of a revision; issue-specific nature of appeals of revised determinations and decisions.**

(a) If a revision is made in a Secretary or intermediary determination or a decision by a reviewing entity after the determination or decision is reopened as provided in § 405.1885 of this subpart, the revision must be considered a separate and distinct determination or decision to which the provisions of §§ 405.1811, 405.1834, 405.1835, 405.1837, 405.1875, 405.1877 and 405.1885 of this subpart are applicable.

(b)(1) Only those matters that are specifically revised in a revised determination or decision are within the scope of any appeal of the revised determination or decision.

(2) Any matter that is not specifically revised (including any matter that was reopened but not revised) may

not be considered in any appeal of the revised determination or decision.

[73 FR 30266, May 23, 2008]

### Subparts S–T [Reserved]

## Subpart U—Conditions for Coverage of Suppliers of End-Stage Renal Disease (ESRD) Services

**AUTHORITY:** Secs. 1102, 1861, 1862(a), 1871, 1874, and 1881 of the Social Security Act (42 U.S.C. 1302, 1320b–8, 1395x, 1395y(a), 1395hh, 1395kk, and 1395rr), unless otherwise noted.

**SOURCE:** 41 FR 22511, June 3, 1976, unless otherwise noted. Redesignated at 42 FR 52826, Sept. 30, 1977.

### §§ 405.2100–405.2101 [Reserved]

#### § 405.2102 Definitions.

As used in this subpart, the following definitions apply:

**Agreement.** A written document executed between an ESRD facility and another facility in which the other facility agrees to assume responsibility for furnishing specified services to patients and for obtaining reimbursement for those services.

**Arrangement.** A written document executed between an ESRD facility and another facility in which the other facility agrees to furnish specified services to patients but the ESRD facility retains responsibility for those services and for obtaining reimbursement for them.

**Dialysis.** A process by which dissolved substances are removed from a patient's body by diffusion from one fluid compartment to another across a semipermeable membrane. The two types of dialysis that are currently in common use are hemodialysis and peritoneal dialysis.

**End-Stage Renal Disease (ESRD).** That stage of renal impairment that appears irreversible and permanent, and requires a regular course of dialysis or kidney transplantation to maintain life.

**ESRD facility.** A facility which is approved to furnish at least one specific ESRD service (see definition of “ESRD service”). Such facilities are:

(a) *Renal dialysis center.* A hospital unit which is approved to furnish the full spectrum of diagnostic, therapeutic, and rehabilitative services required for the care of ESRD dialysis patients (including inpatient dialysis furnished directly or under arrangement). A hospital need not provide renal transplantation to qualify as a renal dialysis center.

(b) *Renal dialysis facility.* A unit which is approved to furnish dialysis service(s) directly to ESRD patients.

(c) *Self-dialysis unit.* A unit that is part of an approved renal transplantation center, renal dialysis center, or renal dialysis facility, and furnishes self-dialysis services.

(d) *Special purpose renal dialysis facility.* A renal dialysis facility which is approved under § 405.2164 to furnish dialysis at special locations on a short-term basis to a group of dialysis patients otherwise unable to obtain treatment in the geographical area. The special locations must be either special rehabilitative (including vacation) locations serving ESRD patients temporarily residing there, or locations in need of ESRD facilities under emergency circumstances.

**ESRD Network organization.** The administrative governing body to the network and liaison to the Federal government.

**ESRD service.** The type of care or services furnished to an ESRD patient. Such types of care are:

(a) *Dialysis service—(1) Inpatient dialysis.* Dialysis which, because of medical necessity, is furnished to an ESRD patient on a temporary inpatient basis in a hospital;

(2) *Outpatient dialysis.* Dialysis furnished on an outpatient basis at a renal dialysis center or facility. Outpatient dialysis includes:

(i) *Staff-assisted dialysis.* Dialysis performed by the staff of the center or facility.

(ii) *Self-dialysis.* Dialysis performed, with little or no professional assistance, by an ESRD patient who has completed an appropriate course of training.

(3) *Home dialysis.* Dialysis performed by an appropriately trained patient at home.